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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/430,177	10/29/1999	UPVAN NARANG	100448.01	6878

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EXAMINER

DI NOLA BARON, LILIANA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 04/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/430,177

Applicant(s)

NARANG ET AL.

Examiner

Liliana Di Nola-Baron

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32,34-51 and 76-144 is/are pending in the application.
- 4a) Of the above claim(s) 4,13,14,26-32,34-49,76-110 and 122-144 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-12,15-25,50,51 and 111-121 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 October 1999 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt of Applicant's amendment and declaration, filed on February 13, 2004, is acknowledged.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-3, 5-12, 15-25, 50, 51 and 111-121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leung (WO 96//40797) in view of Engelson et al. (U.S. Patent 5,531,715).

Leung provides a method for applying polymerization initiators to an applicator tip, comprising dipping the applicator tip in a liquid medium, specifically a low boiling point solvent, containing the initiator and drying the applicator tip (See p. 17, line 18 to p. 18, line 15), and includes anionic surfactants, such as polysorbate 20 and polysorbate 80, poloxamers, cationic surfactants, such as tetrabutylammonium bromide, and amphoteric or zwitterionic surfactants, such as dodecyldimethyl (3-sulfopropyl) ammonium hydroxide, among the initiators used in the invention (See p. 16, lines 18-35). The alkylbenzyldimethylammonium chloride claimed in claim 5 of the instant application, also known as benzalkonium chloride, is a cationic surfactant. Additionally, Leung includes alpha-cyanoacrylates, which are known as antifungals and antibacterial agents, among the polymerizable materials used in the invention (See p. 7, line 23 to p. 8, line 33) and initiators activated by stimulation, such as heat or light, among the initiators,

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which may be applied to the applicator tip (See p. 17, lines 14-28). The crystal violet claimed by Applicant in claims 7-9 of the instant application is activated by light.

Thus, Leung discloses a method comprising dipping an applicator tip in a solution comprising agents as claimed by Applicant in claims 1-3 and 5-12, and drying the applicator tip. Leung teaches that the liquid medium includes non-aqueous solvents, such as ether, acetone and ethanol, and mixtures thereof (See p. 17, lines 24-28). Thus, with regard to claims 1-3, 5-12 and 15-17, Leung provides the general teachings that the liquid medium is preferably a low boiling point solvent (See p. 17, lines 27-28), however, the prior art is deficient in the sense, that it fails to specifically include methanol among the solvents used in the invention. The examiner relies on Engelson et al. (See below) for the teachings that initiators may be dissolved in methanol.

With regard to claim 18, Leung teaches that the initiator on the applicator tip may be present in a variety of concentrations in the medium and the amount depends on process conditions (See p. 17, lines 29-35). Regarding claims 19-25, 50 and 51, Leung teaches that the device of the invention comprises a container and a plunger for forcing the material from the container and an applicator tip (See p. 12, line 36 to p. 14, line 9), and the initiator may be applied to the applicator tip during the fabrication of the tip (See p. 18, lines 1-6) or the applicator tip may be detachable from the applicator container holding the polymerizable material (See p. 14, lines 10-20). Leung teaches that the applicator tip can be made of plastics, foams, rubber or film, and the material may be porous (See p. 15, lines 10-22), and the applicator tip may be dried in a vacuum oven (See p. 18, lines 7-15).

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With respect to claims 111-121, Leung teaches that the polymerizable material used in the invention, comprising alpha-cyanoacrylate (See p. 7, line 23 to p. 8, line 33), are useful as tissue adhesives, sealants for preventing bleeding or covering open wounds, systems for delivering bioactive agents and providing implants (See p. 19, lines 19-34), the tip may be a tube, cannula or catheter, and the container may be a syringe, a tube or a vial (See p. 13, line 20 to p. 14, line 9).

Engelson et al. discloses a method for applying a polymer coating to a catheter, comprising dipping the catheter into a solution comprising initiators dissolved in a solvent, which is preferably a low molecular weight alcohol and ether, especially methanol, ethanol and mixtures thereof (See col. 4, lines 31-67). Thus, ether, ethanol and methanol are considered equivalent in the art.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and compositions disclosed by Leung, by dissolving the initiator in methanol. The expected result would have been a successful method of applying an agent to an applicator tip and successful applicator tips. Because of the teachings of Leung, that the liquid medium is preferably a low boiling point solvent, and the teachings of Engelson et al., that ether, methanol, ethanol and propanol are considered equivalent in the art, one of ordinary skill in the art would have a reasonable expectation that the compositions and methods claimed in the instant application would be successful in providing an applicator tip with the

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desired agent. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Declaration

Applicant's declaration, filed on February 13, 2004, has been fully considered, but it is not persuasive, because the declaration is not commensurate with the scope of the invention.

Applicant provides data showing unexpected results when testing gel set time in the presence or absence of methanol, however, Applicant's claimed invention is not directed to gel setting characteristics or methods of setting gels. The claims in the instant application are drawn to a method of applying an agent to an applicator tip, thus the declaration is not commensurate with the scope of the invention.

Response to Arguments

3. Applicant's arguments filed on February 13, 2004 have been fully considered but they are not persuasive.

4. Applicant argues that the restriction requirements are improper, because there would be no burden on the examiner to search and examine the full scope of the pending claims. This argument is not found persuasive, because burden is shown by the distinct subclasses of the different inventions. Applicant's comments regarding previous searches and examinations are not persuasive because restriction is deemed necessary because of the different subclasses of the different invention and their different subject matter. The requirement is still deemed proper and the restriction requirement was made final in the previous Office action.

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5. Applicant argues that the use of methanol, alone or as a component of a mixture, provides desirable setting characteristics. In response to said argument, it is noted that Applicant's claimed invention is not directed to distribution profile or setting characteristics.

6. In response to Applicant's argument, that Leung fails to disclose methanol among the low boiling point solvents used in the invention, the examiner relies on Engelson et al. (See rejection above) for the teachings that initiators may be dissolved in methanol.

7. In reply to Applicant's argument, that Engelson et al. does not teach applying an agent to an applicator tip, the examiner relies on Leung for the teachings that different agents may be applied to an applicator tip. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

8. In response to Applicant's argument that methanol cannot be ingested and all alcohol solvents are not equivalent in the context of the claimed invention, it is noted that Applicant's claimed invention is not directed to a method of administration of a composition by mouth, and the "comprising" language in the claims allows for the presence of other low boiling point solvents in the compositions used in the method of the claimed invention.

9. In response to Applicant's arguments, that the use of methanol provides unexpected results, Applicant's claimed invention is not directed to gel setting characteristics or methods of setting gels. The claims in the instant application are drawn to a method of applying an agent to

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an applicator tip, thus the unexpected results are not commensurate with the scope of the invention.

10. Applicant argues that Leung fails to teach or suggest that the initiator can be applied by vacuum or pressure. In response to said argument, it is noted that Leung teaches that the device of the invention comprises a container and a plunger for forcing the material from the container (See p. 12, line 36 to p. 14, line 9), and the applicator tip can be dried in a vacuum oven (See p. 18, lines 7-15). Thus, Leung contemplates application of both pressure and vacuum.

Conclusion

11. Claims 1-3, 5-12, 15-25, 50, 51 and 111-121 stand rejected.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 571-272-0592. The examiner can normally be reached on Monday through Thursday, 8:30AM-7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



April 8, 2004

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SUPERVISORY PATENT EXAMINER
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